US009050140B2

(12) United States Patent
Semler et al.

(10) Patent No.: US 9,050,140 B2
(45) Date of Patent: Jun. 9, 2015

(54) APPARATUS FOR STABILIZING VERTEBRAL BODIES

(71) Applicant: **Blackstone Medical, Inc.**, Lewisville, TX (US)

(72) Inventors: **Mark Evald Semler**, McKinney, TX (US); **Francesco Alfredo Larosa**, Neptune, NJ (US)

(73) Assignee: **BLACKSTONE MEDICAL, INC.**, Lewisville, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/651,640**

(22) Filed: **Oct. 15, 2012**

(65) **Prior Publication Data**

US 2013/0041409 A1 Feb. 14, 2013

Related U.S. Application Data

(63) Continuation of application No. 12/190,423, filed on Aug. 12, 2008, now Pat. No. 8,287,571.

(51) **Int. Cl.**
A61B 17/70 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/7004*** (2013.01); *A61B 17/7023* (2013.01); *A61B 17/7025* (2013.01); ***A61B 17/7031*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/7004; A61B 17/7023; A61B 17/7025; A61B 17/7031
USPC 606/254–262
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,743,260 A 5/1988 Burton
5,034,011 A 7/1991 Howland

(Continued)

FOREIGN PATENT DOCUMENTS

FR 2730918 A1 8/1996
FR 2814936 A1 4/2002

(Continued)

OTHER PUBLICATIONS

International Search Report and Written Opinion, PCT/US2009/053600, dated Sep. 29, 2009, 8 pages.

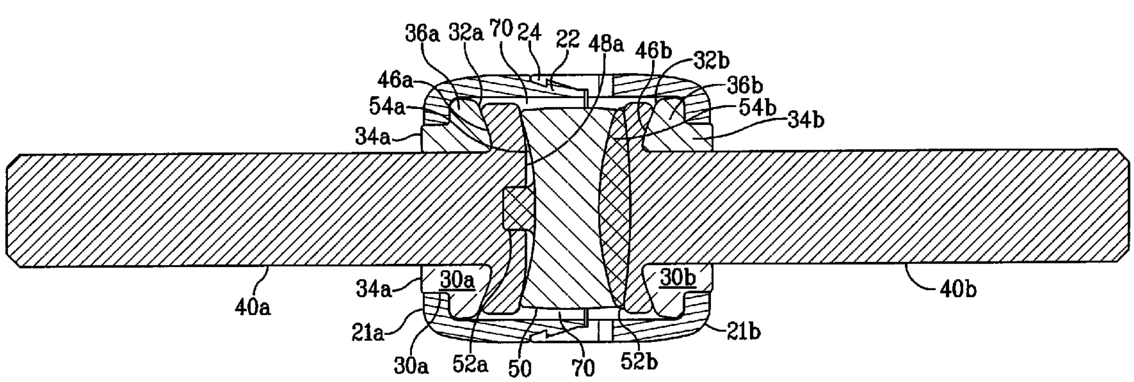
(Continued)

Primary Examiner — Jan Christopher Merene
Assistant Examiner — Atiya Mahmud
(74) *Attorney, Agent, or Firm* — Baker & McKenzie LLP

(57) **ABSTRACT**

A dynamic stabilization apparatus comprises elongated members mounted within the proximal end of anchoring devices that are placed in adjacent vertebral bodies. A flexible element having elastic properties within the applicable range of loading, for example loads that the spine experiences, is disposed between the proximal ends of the elongated members. At least one additional flexible element is mounted about the proximal ends of the elongated members adjacent the central flexible element. A housing encapsulates the proximal ends of the members such that the flexible element and the additional flexible elements are contained therein. As compressive, tensile, angular, shear and rotational forces are applied to the elongated members the central flexible element and the additional flexible elements interact with the elongated members and the housing to allow for motion of the elongated members.

11 Claims, 18 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,092,866 A	3/1992	Breard	
5,180,393 A	1/1993	Commarmond	
5,242,446 A	9/1993	Steffee	
5,282,863 A	2/1994	Burton	
5,375,823 A	12/1994	Navas	
5,415,661 A	5/1995	Holmes	
5,480,401 A	1/1996	Navas	
5,480,442 A	1/1996	Bertagnoli	
5,507,816 A	4/1996	Bullivant	
5,540,688 A	7/1996	Navas	
5,562,737 A	10/1996	Graf	
5,672,175 A	9/1997	Martin	
5,961,516 A	10/1999	Graf	
6,241,730 B1	6/2001	Alby	
6,267,764 B1	7/2001	Elberg	
6,293,949 B1	9/2001	Justis	
6,443,437 B1	9/2002	Beyene et al.	
6,761,719 B2	7/2004	Justis	
6,986,771 B2	1/2006	Paul	
7,029,475 B2	4/2006	Panjabi	
7,083,621 B2	8/2006	Shaolian et al.	
7,125,410 B2	10/2006	Freudiger	
7,282,065 B2	10/2007	Kirschman	
7,291,150 B2	11/2007	Graf	
7,294,129 B2	11/2007	Hawkins et al.	
7,326,210 B2	2/2008	Jahng et al.	
7,326,250 B2	2/2008	Beaurain et al.	
7,338,527 B2	3/2008	Blatt et al.	
7,361,196 B2	4/2008	Fallin et al.	
7,597,027 B2	10/2009	Kwon	
7,763,048 B2	7/2010	Fortin et al.	
7,776,071 B2	8/2010	Fortin et al.	
2004/0002708 A1	1/2004	Ritland	
2004/0049189 A1	3/2004	Le Couedic et al.	
2004/0243127 A1	12/2004	Vincent-Prestigiacomo	
2005/0056979 A1	3/2005	Studer	
2005/0065514 A1	3/2005	Studer	
2005/0096659 A1	5/2005	Freudiger	
2005/0131407 A1	6/2005	Sicvol et al.	
2005/0165396 A1	7/2005	Fortin et al.	
2005/0171540 A1	8/2005	Lim et al.	
2005/0171543 A1	8/2005	Timm et al.	
2005/0182401 A1	8/2005	Timm et al.	
2005/0261685 A1	11/2005	Fortin et al.	
2005/0277922 A1	12/2005	Trieu et al.	
2006/0036240 A1	2/2006	Colleran et al.	
2006/0084984 A1*	4/2006	Kim	606/61
2006/0084991 A1	4/2006	Borgstrom et al.	
2006/0142760 A1	6/2006	McDonnell	
2006/0149238 A1	7/2006	Sherman et al.	
2006/0189984 A1	8/2006	Fallin et al.	
2006/0212033 A1	9/2006	Rothman et al.	
2006/0229609 A1	10/2006	Wang	
2006/0247637 A1	11/2006	Colleran	
2006/0264935 A1	11/2006	White	
2006/0264940 A1	11/2006	Hartmann	
2007/0016190 A1	1/2007	Martinez	
2007/0016193 A1	1/2007	Ritland	
2007/0016201 A1	1/2007	Freudiger	
2007/0049936 A1	3/2007	Colleran et al.	
2007/0055244 A1	3/2007	Jackson	
2007/0093813 A1	4/2007	Callahan, II et al.	
2007/0100341 A1	5/2007	Reglos et al.	
2007/0118122 A1*	5/2007	Butler et al.	606/61
2007/0123866 A1	5/2007	Gerbec et al.	
2007/0135815 A1	6/2007	Gerbec et al.	
2007/0191832 A1	8/2007	Trieu	
2007/0191846 A1	8/2007	Bruneau et al.	
2007/0225710 A1	9/2007	Jahng et al.	
2007/0270814 A1	11/2007	Lim et al.	
2007/0270821 A1	11/2007	Trieu et al.	
2007/0270860 A1	11/2007	Jackson	
2007/0276380 A1	11/2007	Jahng et al.	
2007/0288008 A1	12/2007	Park	
2007/0288011 A1	12/2007	Logan	
2008/0033435 A1	2/2008	Studer et al.	
2008/0058812 A1*	3/2008	Zehnder	606/61
2008/0065078 A1	3/2008	Graf	
2008/0097441 A1	4/2008	Hayes et al.	
2008/0125777 A1	5/2008	Veldman et al.	
2008/0125787 A1	5/2008	Doubler et al.	
2008/0140076 A1	6/2008	Jackson	
2008/0147122 A1	6/2008	Jackson	
2008/0172091 A1	7/2008	Anderson	
2008/0177318 A1	7/2008	Veldman et al.	
2008/0183213 A1	7/2008	Veldman et al.	
2008/0195208 A1	8/2008	Castellvi et al.	
2009/0048631 A1	2/2009	Bhatnagar et al.	
2009/0099608 A1	4/2009	Szczesny	
2009/0234388 A1	9/2009	Patterson et al.	
2009/0326583 A1	12/2009	Moumene et al.	
2010/0069964 A1	3/2010	Lechmann	

FOREIGN PATENT DOCUMENTS

JP	7-289562	7/1995
JP	2005-504566 A	2/2005
JP	2008-502448 A	1/2008
WO	2007/103404 A2	9/2007

OTHER PUBLICATIONS

Japanese Office Action, Application No. 2011-523147, dated Aug. 13, 2013, 6 pages.

Japanese Office Action, JP Application No. 2011-523147, dated Dec. 10, 2013, 4 pages.

Extended European Search Report, Application No. 09807249.9-1506/2320814 PCT/US2009/053600, dated Oct. 7, 2013, 8 pages.

* cited by examiner

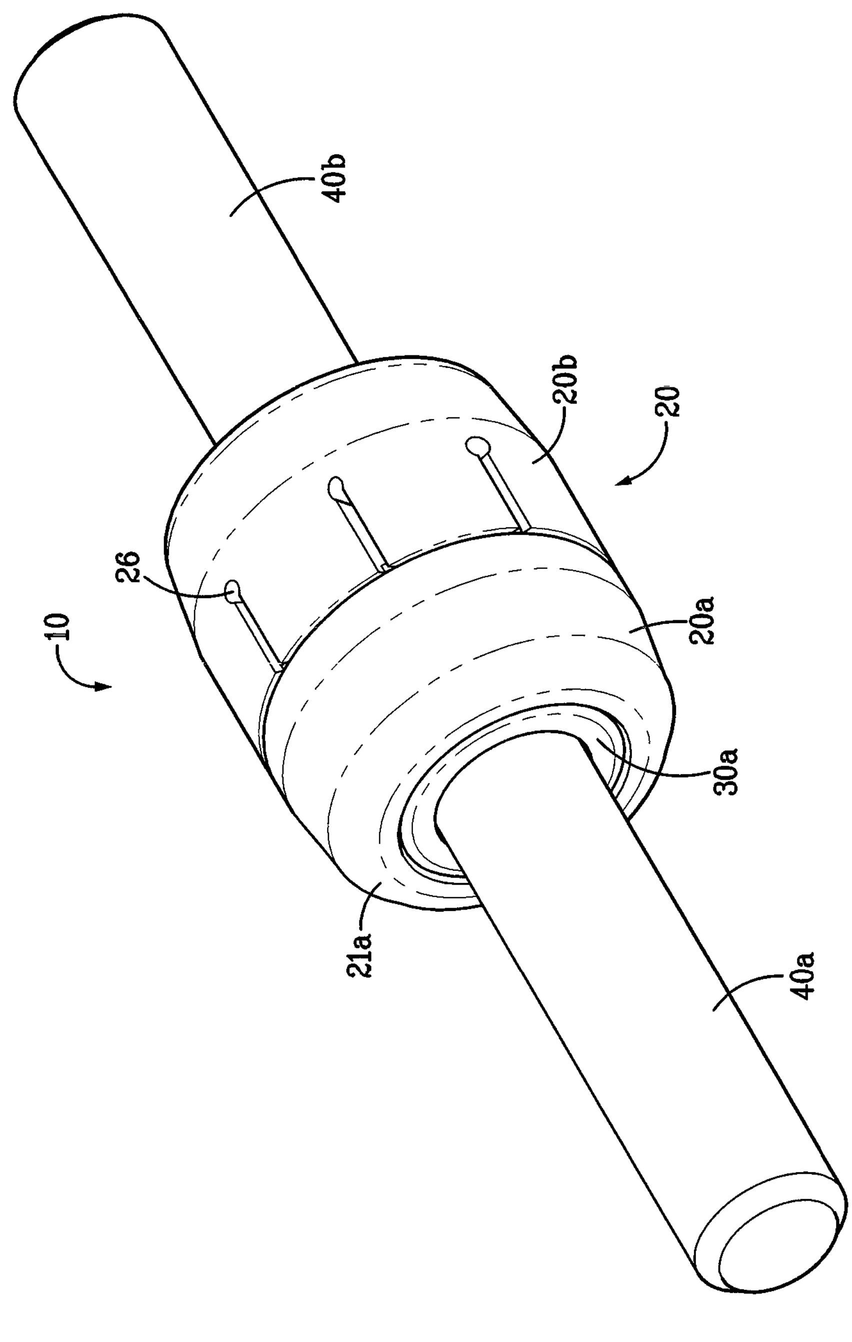


FIG. 1

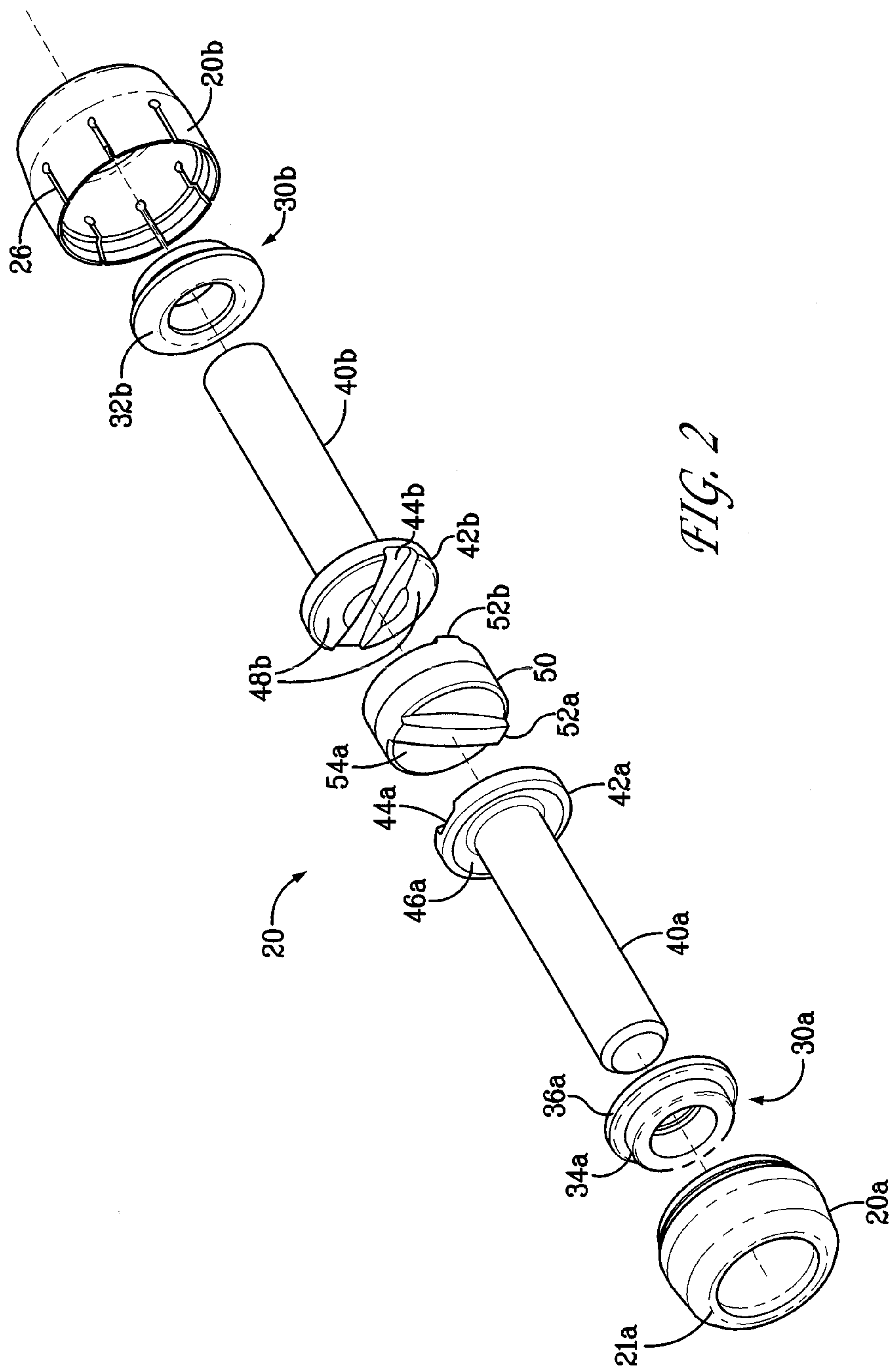

20b
26
30b
32b
40b
44b
42b
48b
52b
50
52a
54a
42a
44a
46a
20
40a
30a
36a
34a
20a
21a

FIG. 2

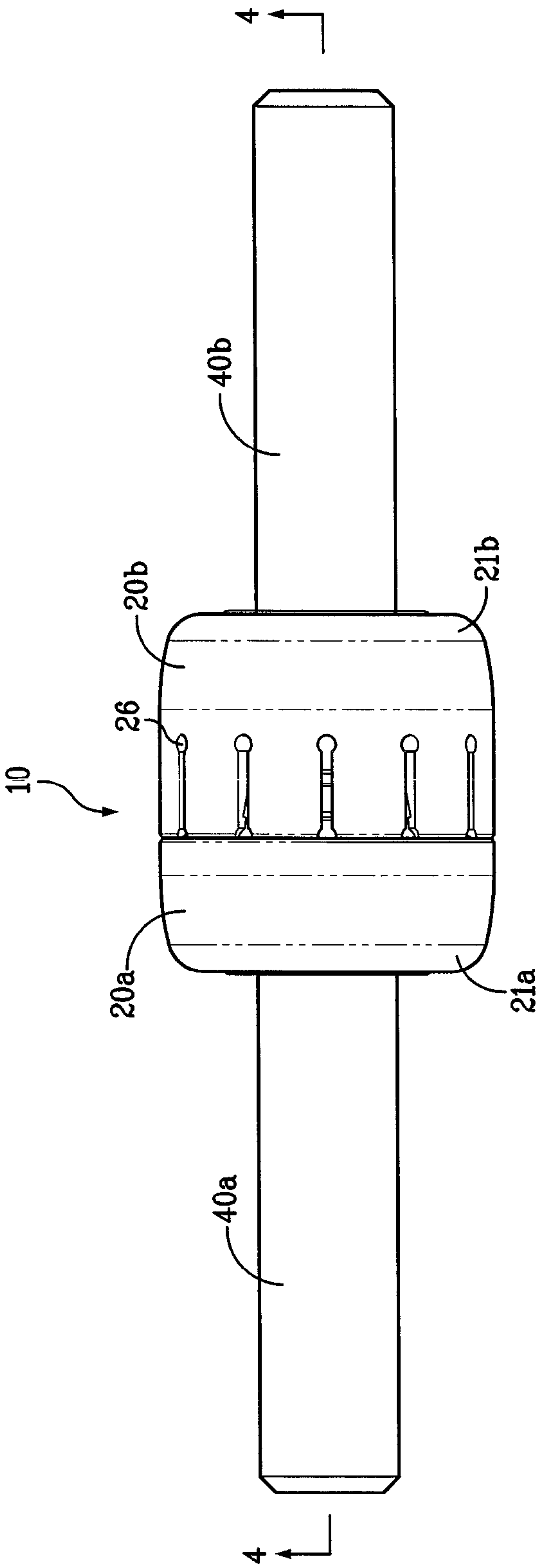


FIG. 3

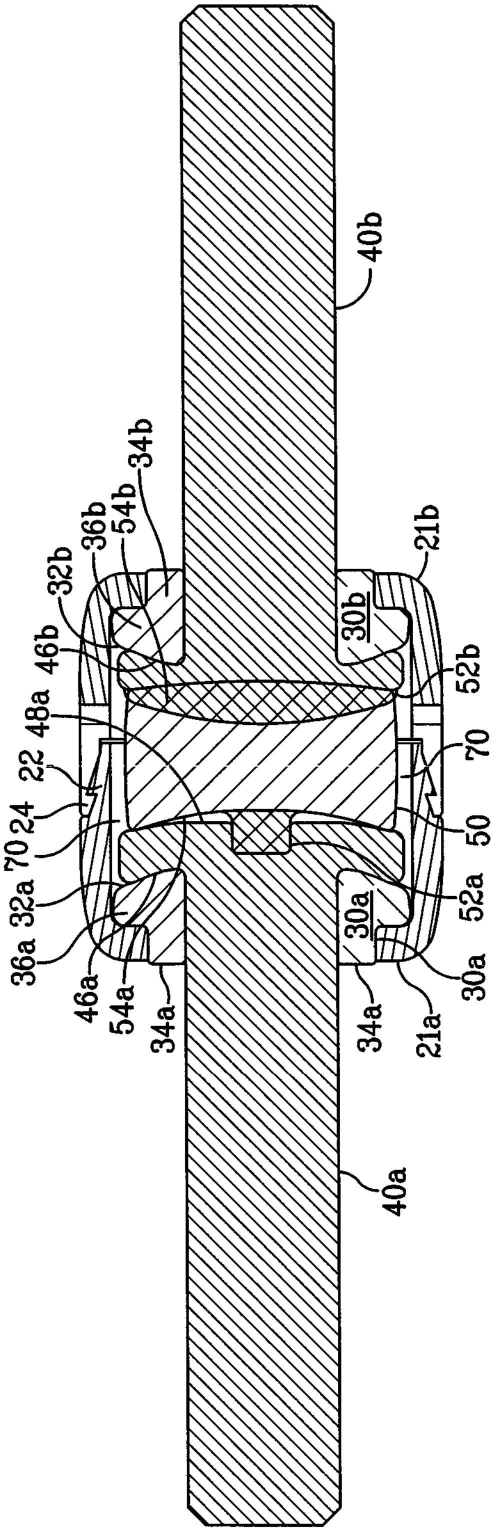

40b
34b
54b
36b
32b
46b
48a
22
24
70
32a
36a
46a
54a
34a
34a
21a
30a
30a
30b
21b
52b
70
50
52a
40a

FIG. 4

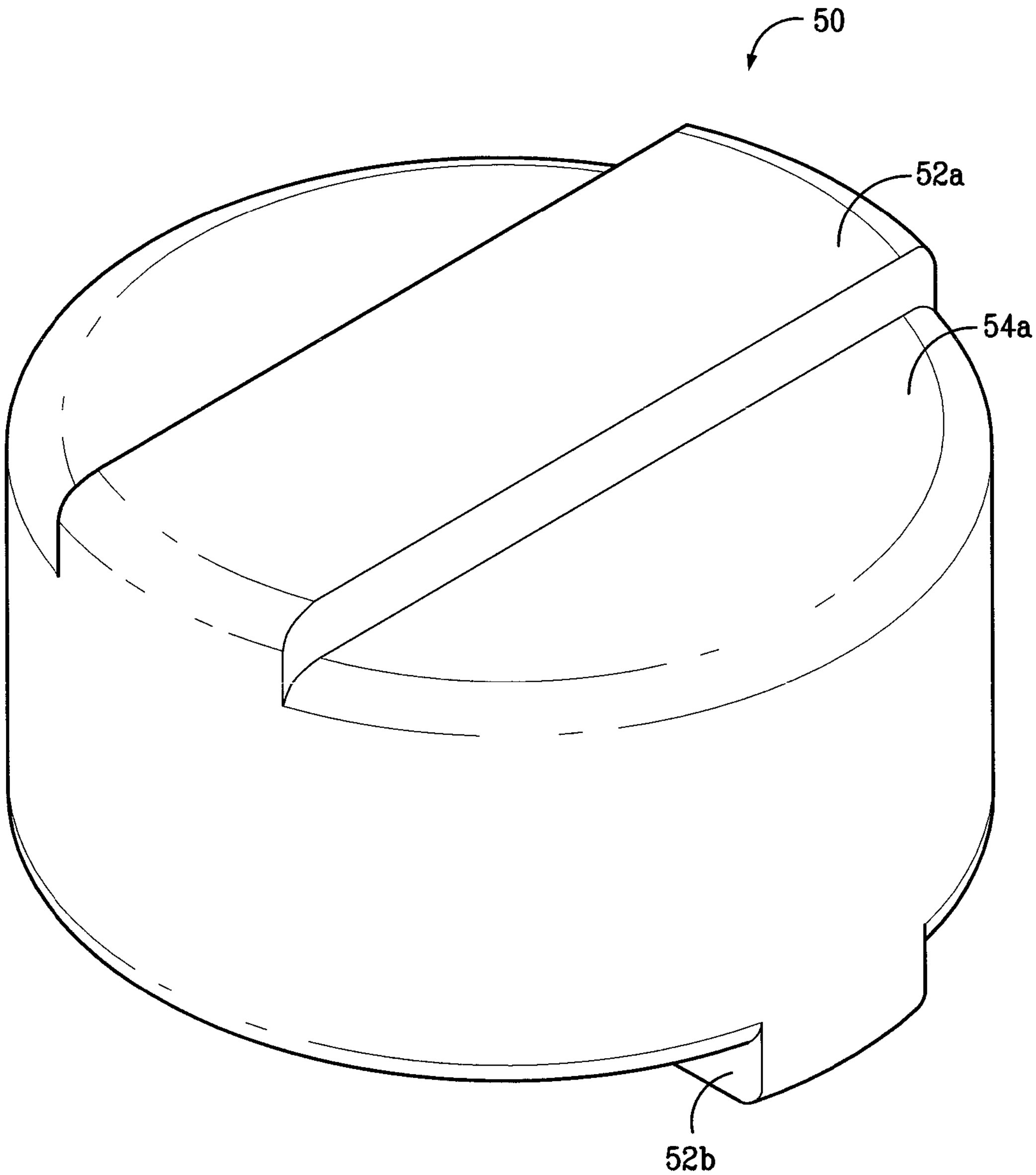


FIG. 5

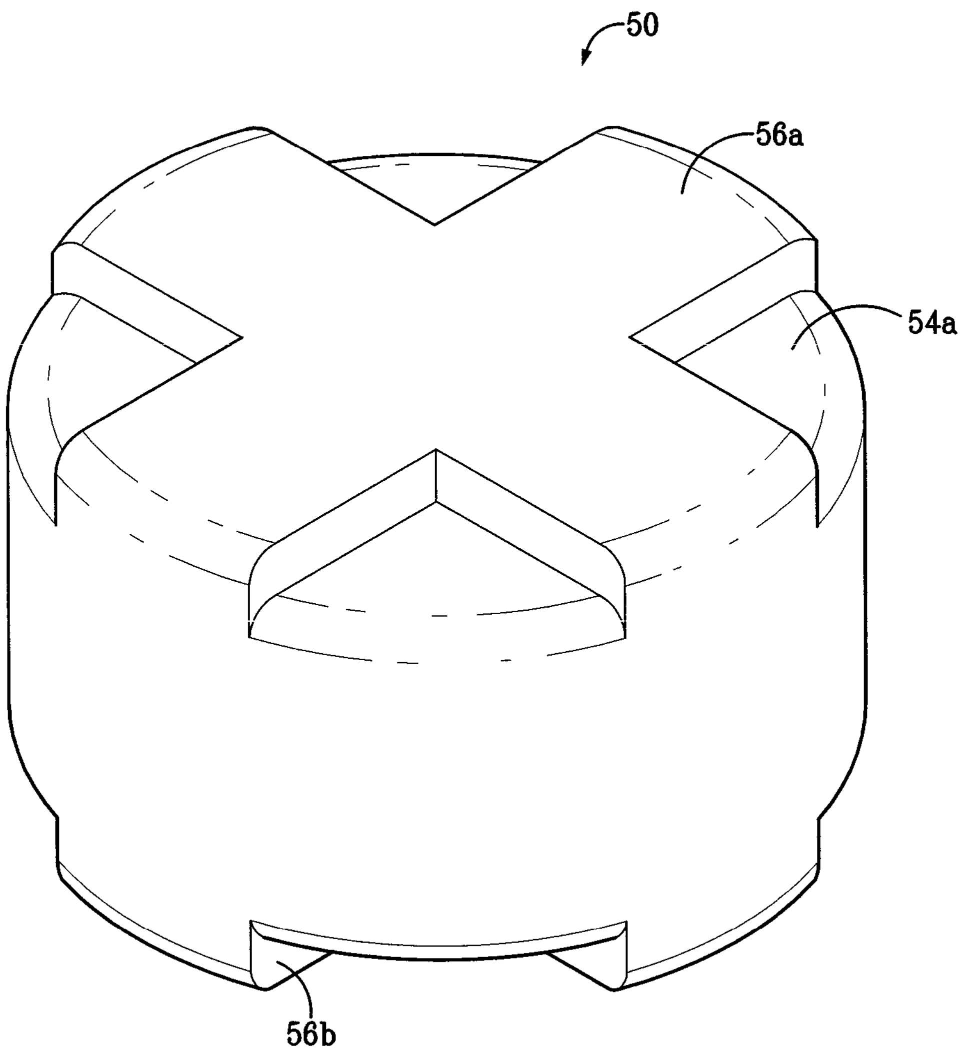


FIG. 6

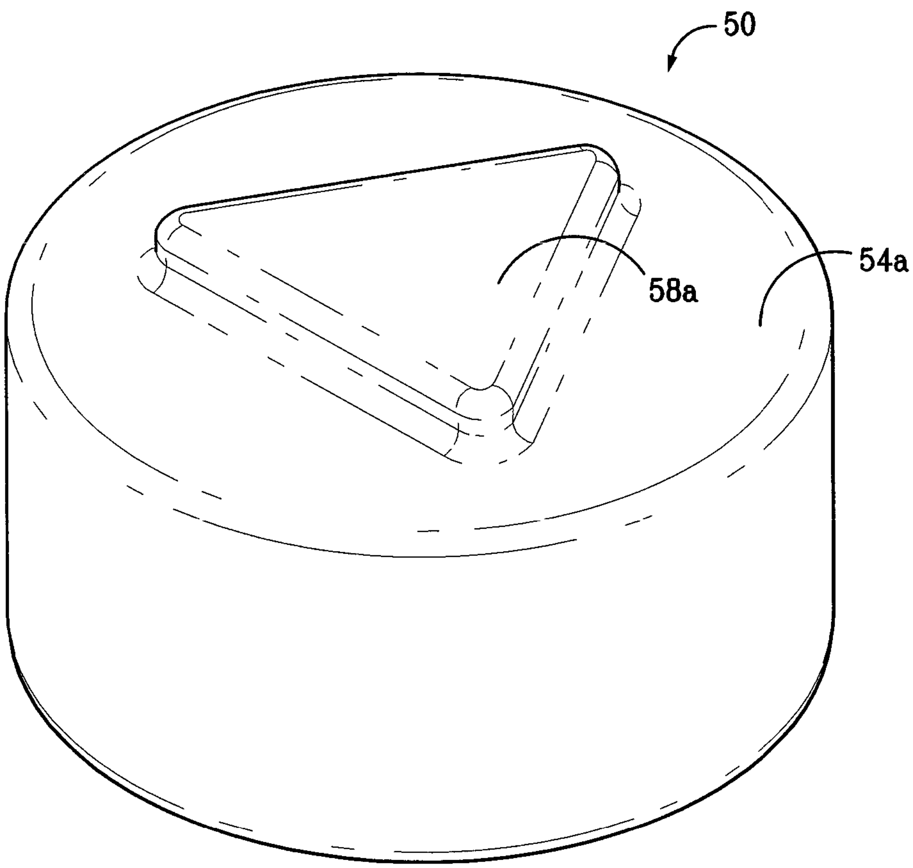


FIG. 7

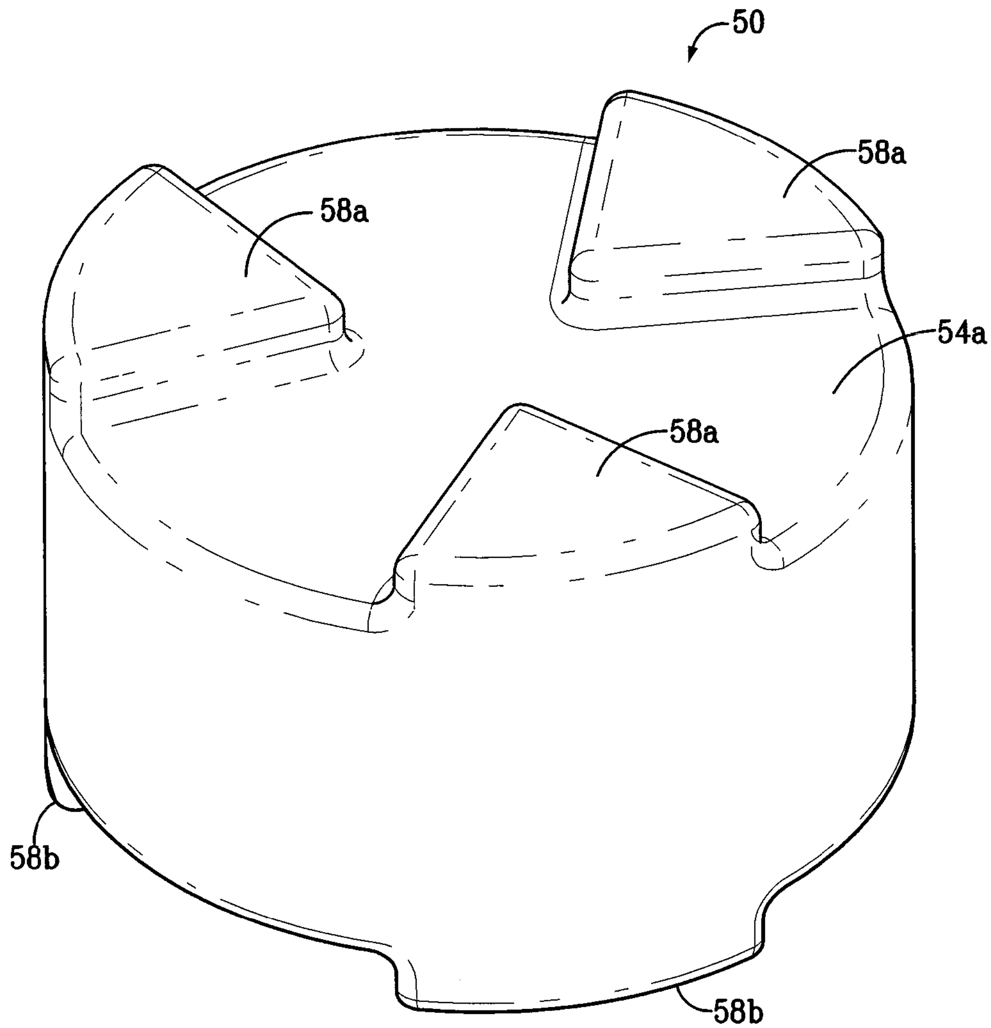


FIG. 8

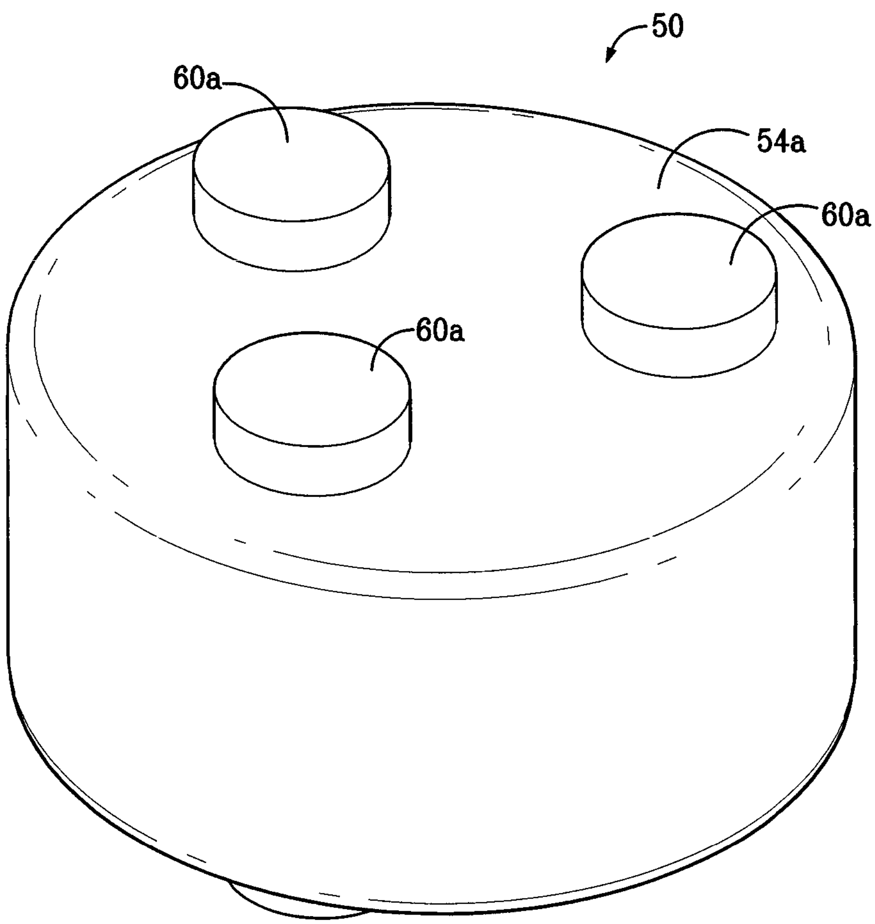


FIG. 9

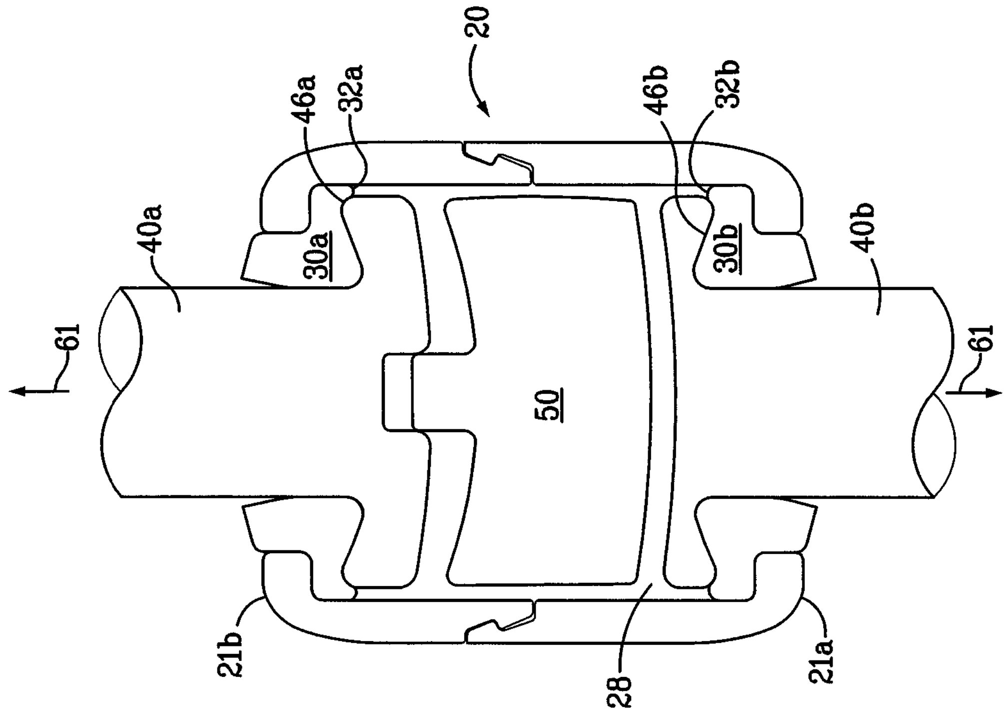


FIG. 10B

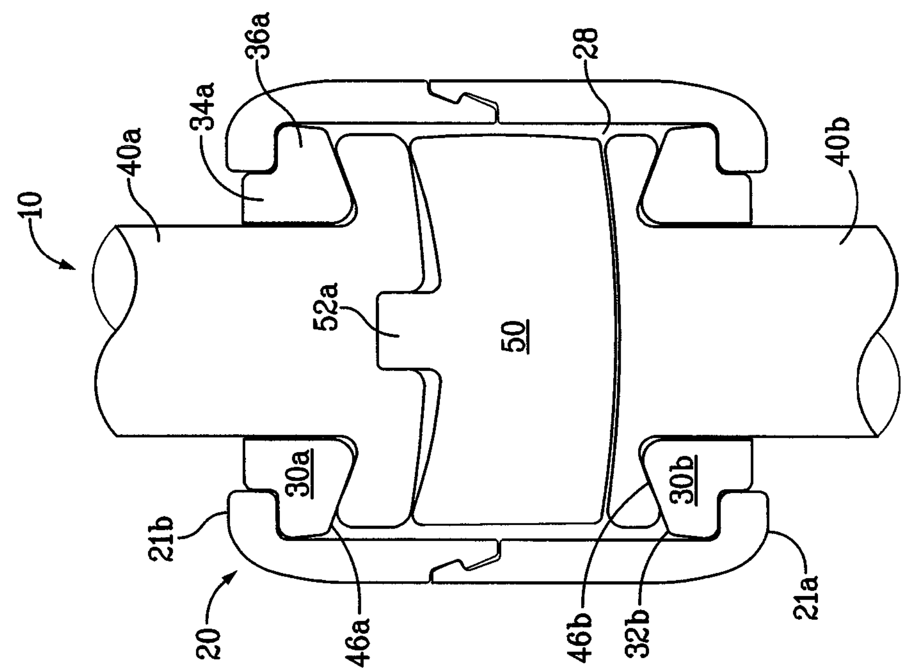


FIG. 10A

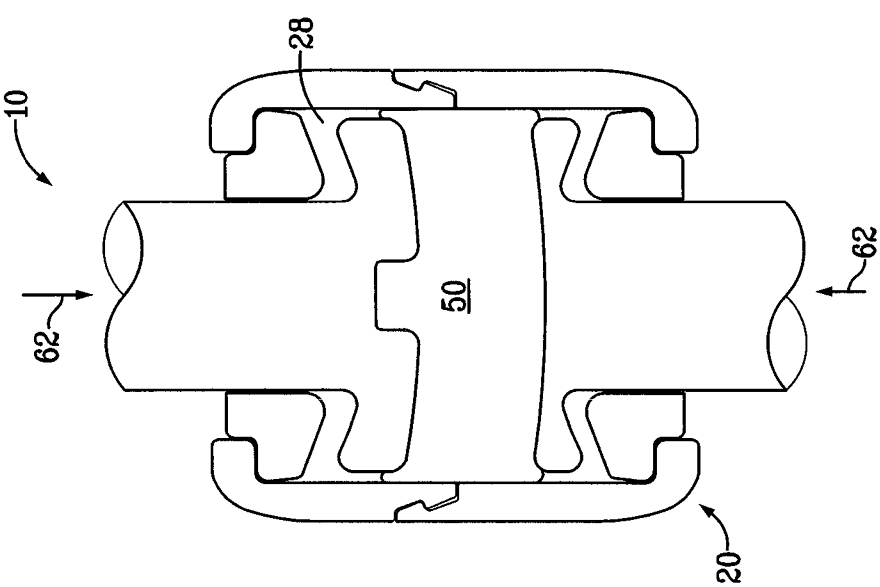


FIG. 11B

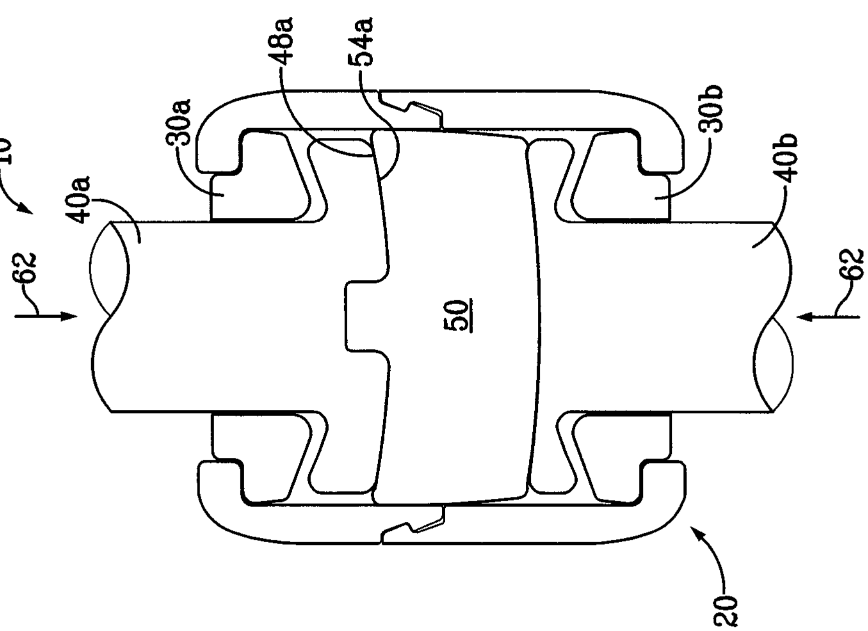


FIG. 11A

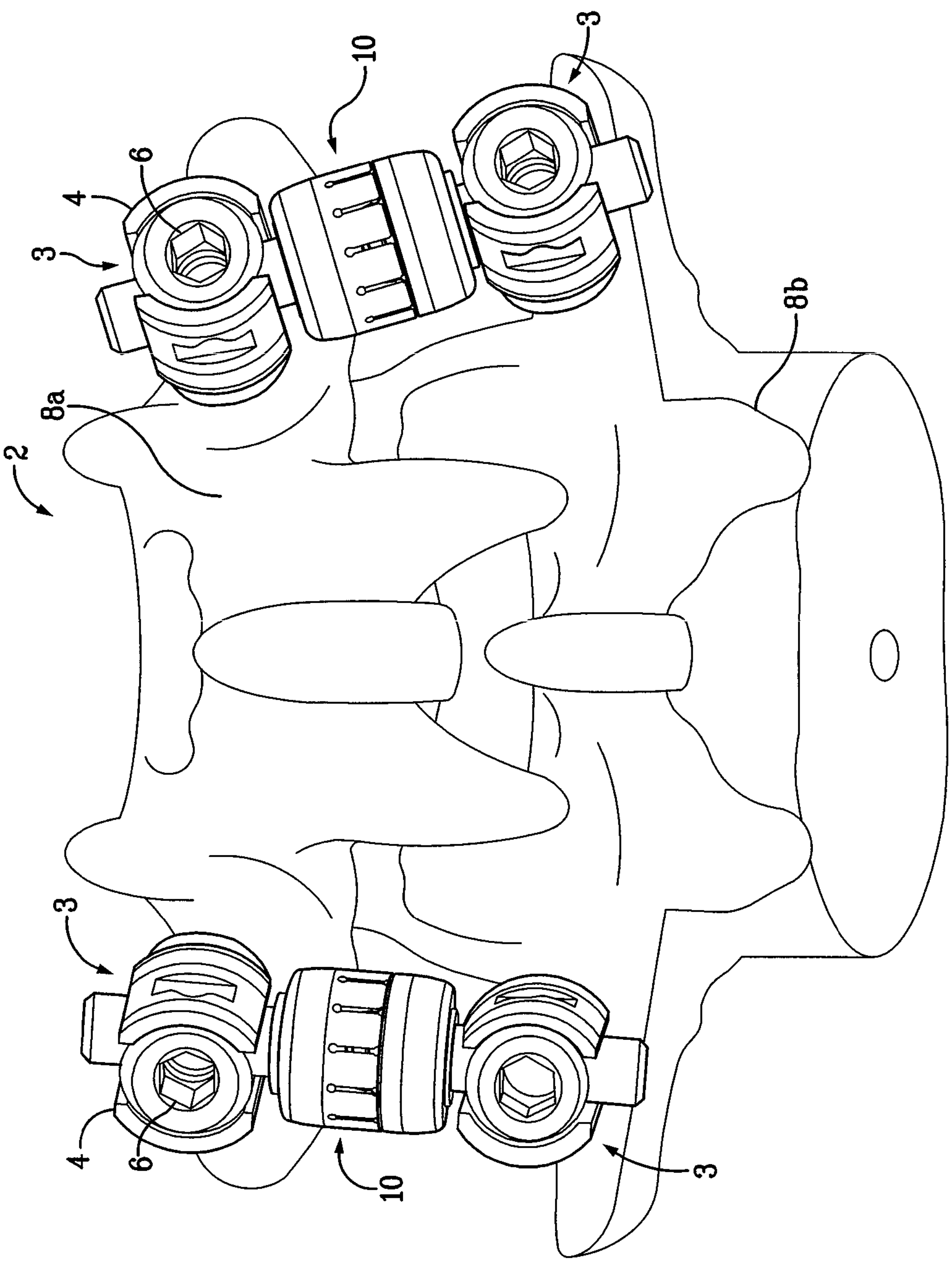


FIG. 12

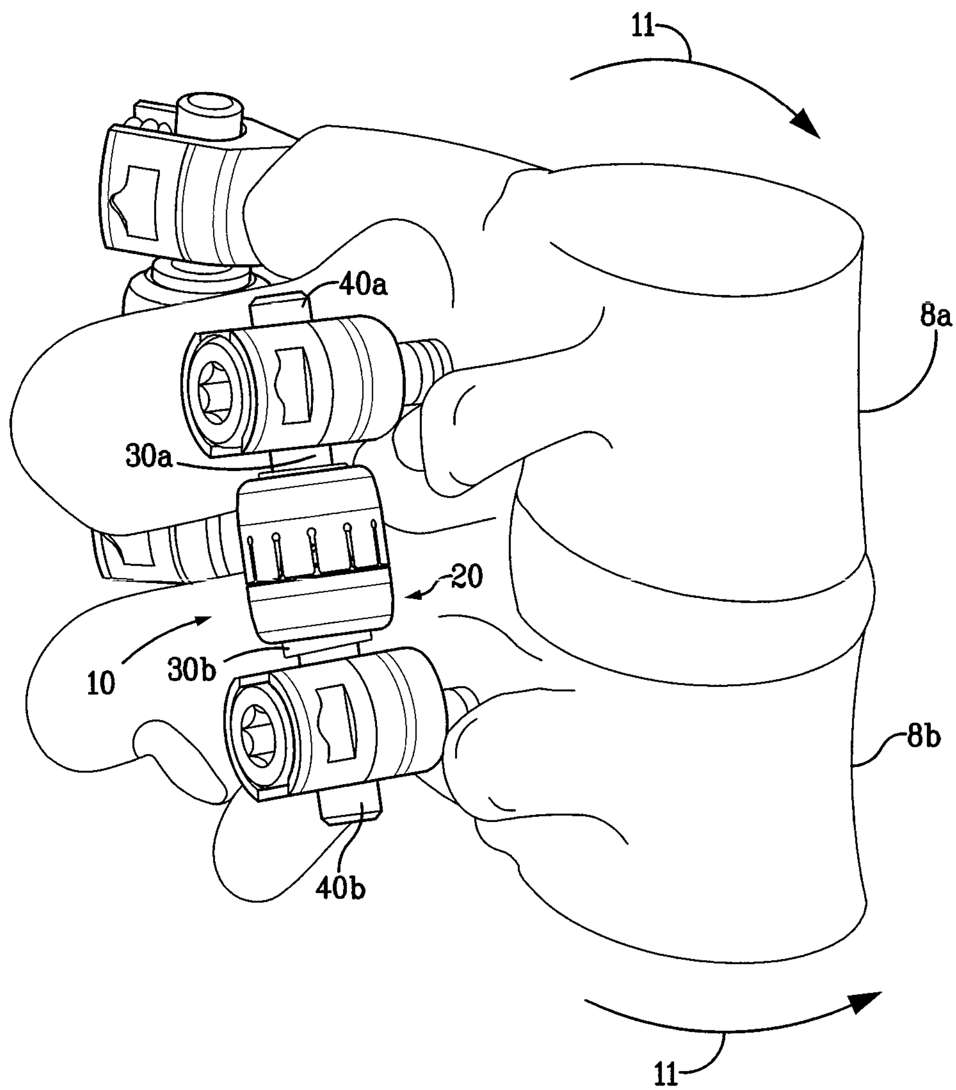


FIG. 13

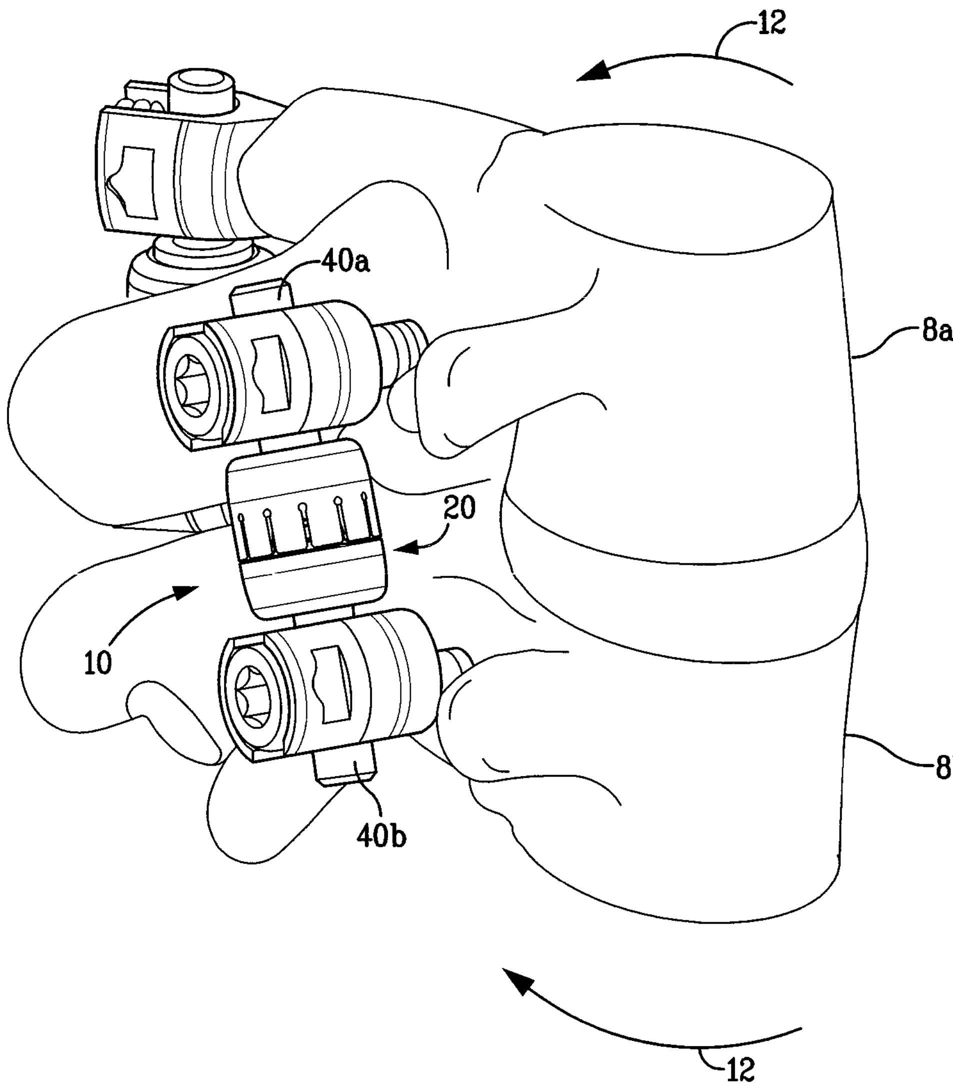


FIG. 14

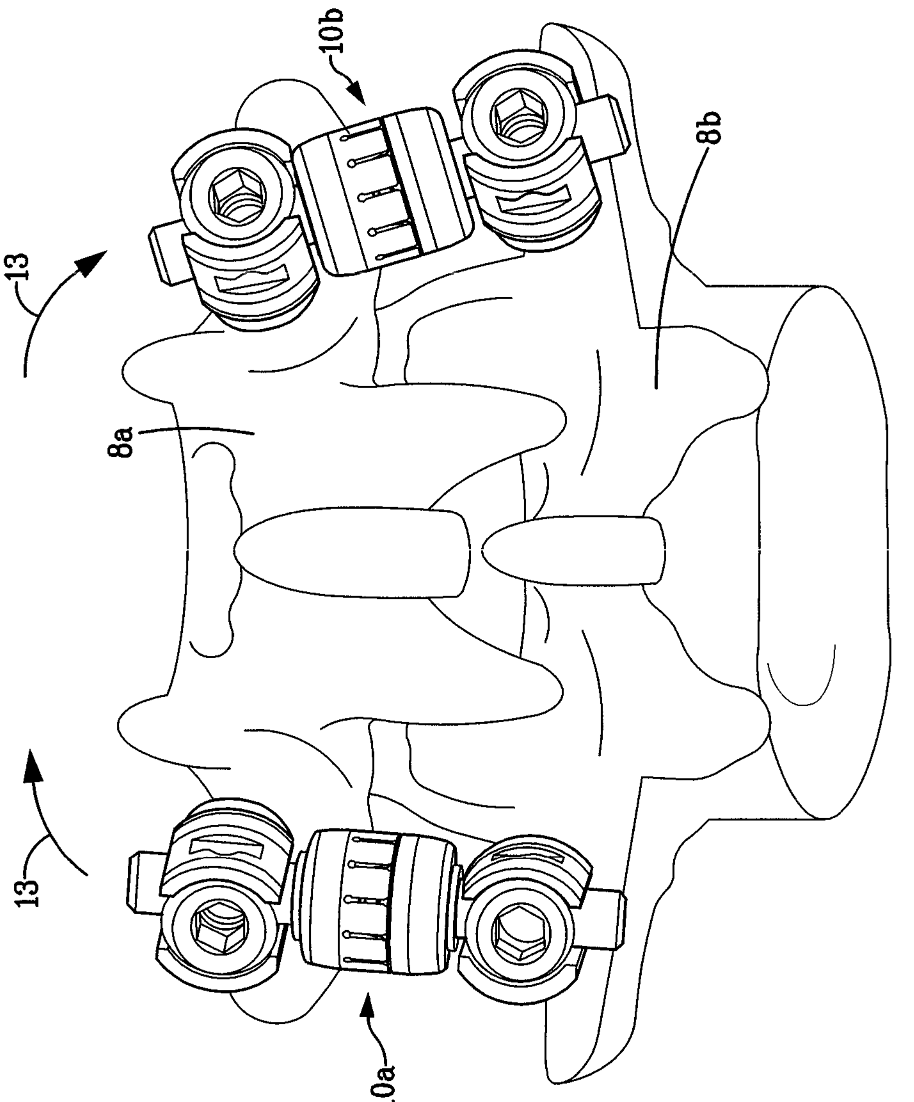


FIG. 15

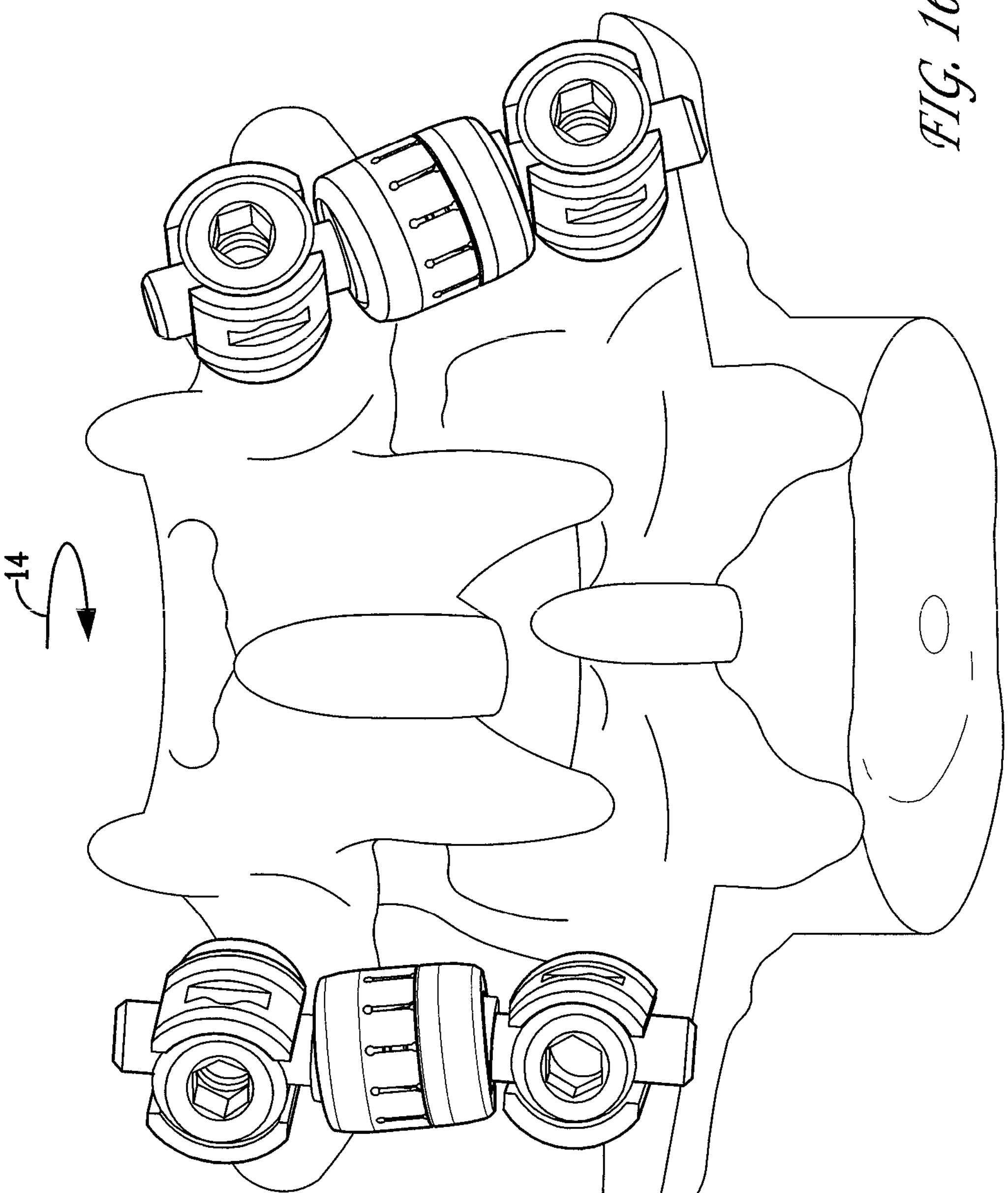


FIG. 16

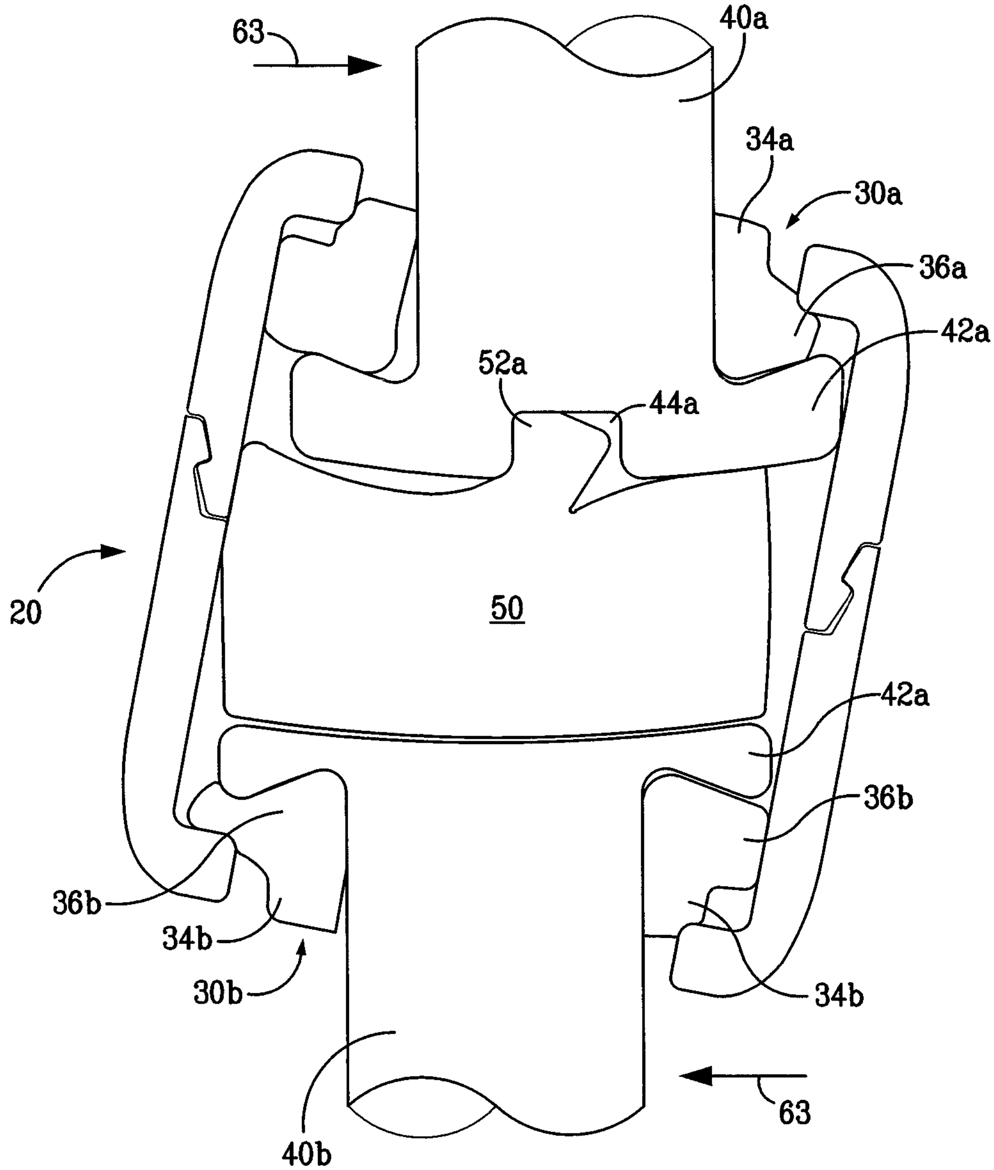

63
40a
34a
30a
36a
42a
52a
44a
20
50
42a
36b
36b
34b
30b
34b
40b
63

FIG. 17

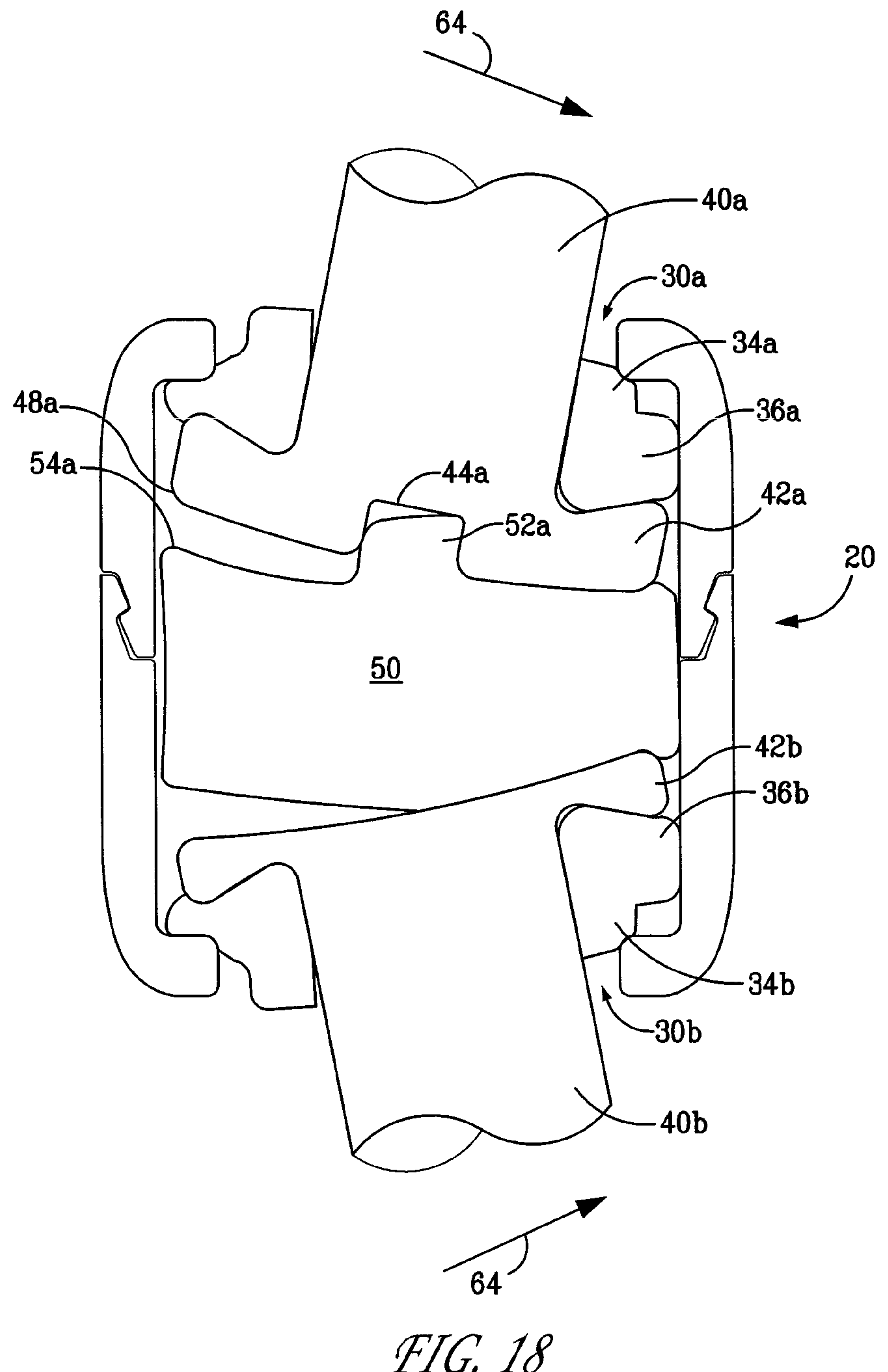

64
40a
30a
34a
36a
48a
54a
44a
52a
42a
20
50
42b
36b
34b
30b
40b
64

FIG. 18

APPARATUS FOR STABILIZING VERTEBRAL BODIES

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation application of U.S. application Ser. No. 12/190,423, which was filed on Aug. 12, 2008 and which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

The present invention relates to stabilization of the vertebrae of the spinal column and, more particularly, to an apparatus whereby securing members are implanted and fixed into a portion of a patient's spinal column and a longitudinal member including flexible, semi-rigid rod-like structures of various cross-sections (hereinafter referred to as "rods") are connected and fixed to the upper ends of the securing members to provide stabilization of the spinal column.

BACKGROUND

Degenerative spinal column diseases, for example, disc degenerative diseases (DDD), spinal stenosis, and spondylolisthesis can be corrected by surgical procedures. Typically, spinal decompression is the first surgical procedure that is performed and results in the reduction of pressure in the spinal canal and on nerve roots located therein. Spinal decompression seeks to remove tissue that is applying pressure to the nerve bundle and thus relieve pain. This can result, however, in weakening the spinal column.

Certain surgical procedures, for example posterolateral fusion whereby adjacent vertebral bodies are fused together is often necessary to restore spinal stability following the decompression procedure. Fusion of adjacent vertebral bodies requires that the bone grow together and employs a bone graft or other biological growth agent. In order to maintain the grafting material in place and preserve stability during bone growth, a spinal fixation device is typically used to support the spinal column until a desired level of fusion is achieved. Depending on a patient's particular circumstances and condition, a spinal fixation surgery can sometimes be performed immediately following decompression, without performing the fusion procedure. The fixation surgery is performed in most cases because it provides immediate postoperative stability and, if fusion surgery has also been performed, it provides support of the spine until sufficient fusion and stability has been achieved.

Conventional methods of spinal fixation utilize a rigid spinal fixation device to support and prevent movement of an injured spinal part. These conventional spinal fixation devices include: fixing screws configured to be inserted into the spinal pedicle or sacrum to a predetermined depth and angle, rods or plates configured to be positioned adjacent to the injured spinal part, and coupling elements for connecting and coupling the rods or plates to the fixing screws such that the injured portion of the spin is supported and held in a relatively fixed position by the rods or plates. The connection units prevent further pain and injury to the patient by substantially restraining the movement of the spinal column.

Because the connection units prevent normal movement of the spinal column, after prolonged use, the spinal fixation device can cause ill effects, such as adjacent level syndrome (transitional syndrome) or fusion disease that result in further complications and abnormalities associated with the spinal column. The high rigidity of the rods or plates used in conventional fixation devices causes these disorders due to the patient's joints being fixated by the nature of surgery. The movement of the spinal joints located above or under the operated area is increased. Consequently, such spinal fixation devices cause decreased mobility of the patient and increased stress and instability to the spinal column joints adjacent to the operated area.

It has been reported that excessive rigid spinal fixation is not helpful to the fusion process due to load shielding. As an alternative, semi-rigid spinal fixation devices have been utilized to address this problem while assisting the bone fusion process. For example, U.S. Pat. No. 5,375,823—Navas and U.S. Pat. No. 6,241,730—Alby each disclose a piston configuration mounted between fixing screws having a flexible material or spring element enclosed within a sleeve allowing for axial dampening Although providing for a greater range of motion than a fixed rod, these devices fail to accommodate for a full range of physiological motion, for example axial torsion or twisting, and are not well-suited for spinal stabilization absent fusion. Thus, in the end these devices do not fully prevent the problem of rigid fixation resulting from fusion.

To solve the above-described problems associated with rigid fixation, semi-rigid and generally flexible devices have been developed. U.S. Publication No. 2006/0264940—Hartmann discloses a flexible spring element connected to a rod and an axially opposed hollow body. The spring element and hollow body have corresponding bores that receive a clamping element. The clamping element has a convex face that abuts the end wall of the internal bore of the spring element during deformation of the spring element under axial loading of the device. The shape of the end of the clamping element controls the spring characteristics of element. While this device functions to provide a greater range of motion during compression it relies upon the spring element as a load bearing structure in tension. This is not an optimal design to handle the long-term cyclical loading the device will experience when implanted.

U.S. Pat. No. 5,672,175—Martin discloses a flexible spinal fixation device which utilizes a flexible rod made of metal alloy and/or a composite material. Additionally, compression or extension springs are coiled around the rod for the purpose of providing de-rotation forces on the vertebrae in a desired direction. However, this approach is primarily concerned with providing a spinal fixation device that permits "relative longitudinal translational sliding movement along [the] vertical axis" of the spine and has a solid construction with a relatively small diameter in order to provide a desired level of flexibility. Because they are typically very thin to provide suitable flexibility, such a rod is prone to mechanical failure and have been known to break after implantation in patients. Similarly, U.S. Publication No. 2007/0270814—Lim shows a vertebral stabilizer that has mobility during compression, extension and rotation. A connecting member such as flexible rods, cables or braided steel are anchored at their distal and proximal ends to engaging portions and are coaxially located within a flexible member. While the connecting members can bend to accommodate shear when the spine is twisted this device has been shown to fail due to fatigue once implanted.

There is no spinal fixation device that can provide for a full range of physiological motion when implanted in a patient. In addition, few devices that attempt to accommodate a range of physiological motion can withstand long-term loading conditions. Therefore, there is a need for an improved dynamic spinal fixation device.

SUMMARY

Elongated members such as rods, plates and the like are often mounted to span vertebral bodies in order to provide stability to localized regions of the spine. These devices are typically mounted to the vertebral bodies via an anchoring device such as a member having threads at its distal end, allowing for attachment to the spine and a proximal end that accepts the elongated member. For example, at least two threaded members are placed in adjacent vertebral bodies and the elongated members are mounted to the proximal end of threaded members so as to span the vertebral bodies. Rigid elongated bodies are typically employed in order to prevent motion between the vertebral bodies.

According to the invention, a dynamic stabilization apparatus is provided. The apparatus comprises elongated members such as rods mounted within a housing. The elongated members are mounted within the proximal end of anchoring devices that are placed in adjacent vertebral bodies. A central flexible element having elastic properties within the applicable range of loading, for example loads that the spine experiences, is disposed between the proximal ends of the elongated members. At least one additional flexible element is mounted about the proximal ends of the elongated members adjacent the central flexible element. The housing encapsulates the proximal ends of the members such that the central flexible element and the additional flexible elements are contained therein. As compressive, tensile, angular, shear and rotational forces are applied to the elongated members the central flexible element and the additional flexible elements interact with the elongated members and the housing to allow for motion of the elongated members. The degree of permissible motion may be varied, for example, by varying the material from which the flexible members are constructed.

The housing may be generally cylindrical and has openings at each end for receiving the elongated members there through. In one embodiment of the invention, the housing is constructed from a generally rigid material that will not deform under the physiological loading encountered within the spine. The housing may be formed from a first and a second casing wherein each of the casings have an opening therein. The casings include an engagement feature such that after the elongated members are inserted through the openings the casings are engaged together to assemble the apparatus.

In one embodiment of the invention the proximal ends of the elongated elements are larger than the central and distal portions of the elongated member. For example, one or both of the proximal ends are flanges. The flange includes an inward surface facing the central flexible element and an outward surface facing the distal end of said elongated member. The inward surface may be generally concave and contacts an outer facing surface of the central flexible clement that is convex. Alternatively, the inner surface of the flange may be convex while the contacting or outer surface of the central flexible element is concave. A variety of shapes for the two surfaces may be employed including having both surfaces be flat.

The central flexible member may be constructed from a polymer and has a first and a second outward facing surface. The central flexible member resists rotational and compressive forces. The inward surface of each of the flanges contacts the outer facing surfaces of the central flexible element. Protrusions located on either the outward surface of the central element or the inward surface of the flanges engages with corresponding recesses to form an anti-torsional coupling. As the elongated members are rotated about their axis in opposite directions the engagement of the protrusions within the recesses causes the central flexible element to elastically deform, resisting the motion. In addition, as the elongated members experience a compressive force the flanges engage the central flexible element. The central flexible element is compressed resisting while allowing motion of the elongate members. Eventually the central flexible element deforms such that it contacts the housing further increasing the resistance to the motion of the elongated members.

The outward surface of the proximal end of the elongate members or the flange contacts a surface of the additional flexible element. A variety of shapes can be employed for the outward surface of the flange and the corresponding contacted surface of the additional flexible element. The shaping of these surfaces may be varied in order to create a desired dynamic response. As with the central element, the additional flexible elements may be constructed from a polymer. The additional flexible elements serve as an axial and radial buffer between the housing and the elongated members. For example, as the elongated members are subjected to an axial or radial force, the flange pushes on and deforms the additional flexible member which resists the motion of the elongated members. Varying the elastic properties of the central and flexible members allows the load-displacement response of the apparatus to be customized.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and advantages of the invention will be apparent to those of ordinary skill in the art from the following detailed description of which:

FIG. **1** is an isometric view of to an embodiment of the present invention;

FIG. **2** is an exploded view of the components of an embodiment of the present invention.

FIG. **3** is a side view of an embodiment of the present invention.

FIG. **4** is a view of an embodiment of the present invention taken along line **4-4** of FIG. **3**.

FIG. **5** is an isometric view of an embodiment of the central element of the present invention.

FIG. **6** is an alternative embodiment of the central element of the present invention.

FIG. **7** is an alternative embodiment of the central element of the present invention.

FIG. **8** is an alternative embodiment of the central element of the present invention.

FIG. **9** is an alternative embodiment of the central element of the present invention.

FIG. **10**A is a cross section view showing an embodiment of the present invention in an unloaded state.

FIG. **10**B is a cross section view showing an embodiment of the present invention under tension.

FIG. **11**A is a cross section view showing an embodiment of the present invention in compression.

FIG. **11**B is a cross section view showing an embodiment of the present invention in a further compressed state.

FIG. **12** is a posterior view showing an embodiment of the present invention placed on a section of the spine.

FIG. **13** is a side view showing an embodiment of the present invention placed on a section of the spine whereby the section of the spine is in flexion.

FIG. **14** is a side view showing an embodiment of the present invention placed on a section of the spine whereby the section of the spine is in extension.

FIG. **15** is a posterior view showing an embodiment of the present invention placed on a section of the spine whereby the section of the spine experiences lateral bending.

FIG. **16** is a posterior view showing an embodiment of the present invention placed on a section of the spine whereby the section of the spine experiences axial rotation.

FIG. **17** is a cross section view showing an embodiment of the present invention actuated under shear.

FIG. **18** is a cross section view showing an embodiment of the present invention angulated.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

An implantable dynamic apparatus for stabilizing a desired region of the spine will be described with reference to FIGS. **1-18**. As shown in FIGS. **1-4** the apparatus **10** of the present invention generally comprises elongated members **40***a, b* mounted within a housing **20**. A central element **50** having elastic properties is disposed between the proximal ends of the two elongated members **40***a, b*. At least one additional flexible or compressible element **30***a, b* is mounted about the proximal end of the elongated members **40***a, b* adjacent the central element **50**. The housing **20** encapsulates the proximal ends of the elongated members **40***a, b* such that the central element **50** and the at least one additional flexible or compressible element(s) **30***a, b* are contained therein.

The elongated members **40***a, b* may be constructed from materials having sufficient strength and rigidity to resist fracture and plastic deformation under the loads experienced by the spine. Materials such as titanium, titanium alloy, stainless steel or a polymer such as PEEK or carbon fiber may be employed. The elongated members **40***a, b* may have a variety of shapes such as cylindrical or polygonal and need not both have the same shape. The construction of the components of the apparatus **10** may be varied to meet the particular conditions of the patient in which the apparatus **10** will be utilized. For example, the material used to construct the central element **50** may be varied or the size and shape or the elongated members **40***a, b* can be varied such that each member has a different shape or is constructed from a different material.

As shown in FIG. **12**, one or more of apparatus **10** can be mounted between adjacent vertebral bodies **8***a, b* in order to provide stability to localized regions of the spine **2**. Typically, stabilization devices such as apparatus **10** are mounted to the vertebral bodies **8***a, b* via an anchoring device **3**. The device may comprise a member having threads at its distal end, not shown in the drawings that allow for attachment to the honey tissue of the spine and a proximal end **4** that accepts the distal ends of elongated members **40***a, b*. Alternatively, the distal end may comprise a clamp or other gripping surface. A retaining member **6** locks the distal ends of the elongated members **40***a, b* to the anchoring devices **3**. As will be described in greater detail below, when the spine experiences the normal range of physiological motion the central element **50** and the additional flexible or compressible elements **30***a, b* interact with the elongated members **40***a, b* and the housing **20** to stabilize the spine while allowing for controlled movement of the adjacent vertebral bodies **8***a, b*.

As shown in FIGS. **2** and **4**, the central flexible element **50** is situated between the proximal ends of the elongated members **40***a, b*. The shape of the central element **50** is designed to maximize contact with the proximal ends of the elongated members **40***a, b* as described in greater detail below, while leaving a space **70** between element **50** and the housing **20** to allow for distortion of the shape of the central flexible element **50** when elongated members **40***a, b* are moved inward.

The central flexible element **50** can be homogeneous or made as a composite to tailor its performance to the particular loading apparatus **10** experiences when implanted. In one embodiment of the present invention, the central flexible element **50** is constructed from an incompressible elastomer such that as elongated members **40***a, b* are moved inwards, element **50** experiences transverse strain in response to axial strain. A flexible material having a durometer range of 30-65 on the Shore D scale or 20-95 on the Shore A scale and an elongation at break in the range of 200-600% per ASTM D-638 may be utilized to construct the central flexible element **50**. The material utilized preferably is biocompatible and exhibits a consistent dynamic response and resists wear over the millions of loading cycles experience by the apparatus **10** when implanted in the spine. One such material is Polycarbonated Polyurethane or PCU known commercially as Chronoflex. One grade of Chronoflex that has been shown to function with the present invention is Chronoflex C 55D.

As shown in FIG. **10**A the central element is unexpanded when the apparatus **10** is in a neutral, unloaded position. As shown in FIGS. **11**A and B, when members **40***a, b* are moved in the direction of arrows **62**, such as would be experience when the spine is extended, element **50** eventually expands into space **70** contacting the inner wall of housing **20**. With further movement of the members **40***a, b*, the element **50** further expands into interstitial space **28**. The expansion of the element **50** into spaces **70** and under certain conditions space **28** causes an exponential increase in resistance to compressive loading. This allows for the restricted movement of the adjacent vertebral bodies that apparatus **10** spans while also providing stability thereto.

As shown in FIG. **2**, the proximal ends of the elongated arms or members **40***a, b* are larger than the central and distal portions of the elongated members **40***a, b*. For example, one or both of the proximal ends comprise flanges **42***a, b*. The flanges **42***a, b* include outer surfaces **46***a, b* facing the distal end of the elongated members **40***a, b* and inner surfaces **48***a, b* that face the central element **50**. As shown in FIG. **4**, the inner surfaces **48***a, b* of the flanges **42***a, b* may be convex while the opposing surfaces **54***a, b* of the central element **50** are concave. Alternatively, the inward surfaces **48***a, b* may be generally concave while the opposing surfaces **54***a, b* are convex. In addition, a variety of shapes for the two surfaces may be employed including having both surfaces be flat or having non complimentary geometries. The shape of the surfaces **48***a, b* and **54***a, b* will impact the angular and shear displacement between the elongated members **40***a, b*. The convex and concave shape of surfaces **48***a, b* and **54***a, b* respectively act as a rotating joint allowing for articulation as apparatus **10** experiences angular and shear loading.

The central flexible element **50** may include one or more features on surfaces **54***a, b* that allows it to interface with the flanges **42***a, b*. As shown in FIGS. **2** and **5**, the central element **50** includes two ribs **52***a, b* on the outer surfaces **54***a, b*. Each flange **42***a, b* includes a slot **44***a, b* that corresponds to the geometry of the ribs **52***a, b* such that the ribs are received and under certain conditions engaged therein. As the elongated members **40***a, b* are twisted under torsional loading, the ribs **52***a, b* engage the slots **44***a, b* acting to resist the twisting movement. The ribs **52** *a, b* are oriented orthogonally to each other to allow for more consistent performance in angulation and shear. This also allows for implantation of the device without regard to orientation.

Over time the frictional and compressive forces resulting from the contact between flanges **42***a, b* and central element **50** will adversely affect the dynamic performance of element **50** due to wear and degredation. Although the central element **50** is constructed from a material that resists wear, the geometry of the features on surfaces **54***a, b* may be varied in order to increase the durability of the central clement **50**. FIGS. **6-9** illustrate examples of geometries that may be employed. FIGS. **2** and **6** shows a plurality of ribs **56***a, b* disposed on the surface **54***a, b* such that the amount of surfaces **54***a, b* that contact the inner surfaces **48***a, b* are minimized. FIG. **7** shows the central flexible element **50** with centrally located polygons **58** *a, b*. In addition, the polygons **58** *a, b* may have any number of sides, for example, forming a star with a plurality of points. As shown in FIG. **8** the central flexible element **50** has a plurality of polygons **58***a, b* located at the perimeter of central element **50**. In this embodiments polygons **58***a, b* are shown with three sides but could be any number of sides and need not match each other and not be arranged in any pattern.

FIG. **9** shows the central flexible element **50** with a plurality of cylindrical protrusions **60***a, b* positioned in a pattern about the surface **54** *a, b* of the central flexible element **50**. As with the other embodiments, the cylindrical protrusions may be arranged in any manner and need not follow a pattern. In all of the shown embodiments in FIGS. **5-9**, the type of engagement features on one side of the central flexible element **50** need not match the engagement features on the opposite side. For example one surface **54***a* a may have a cruciform **56** a while the other surface **54***b* has multiple polygons **58** *b*. In addition, the surfaces **54***a, b* can each have different types of features such as polygons and cylindrical protrusions thereon.

As shown in FIGS. **2** and **4**, a flexible element or elements **30***a, b* is mounted about the proximal end of one or both of the elongated members **40***a, b*. The flexible elements **30***a, b* comprise a collar **34***a, b* and a central region **36***a, b* each interacting with housing **20** depending upon the movement of the elongated members **40***a, b*. For example, the central region **36***a, b* of the flexible elements **30***a, b* is acted upon when the elongated members **40***a, b* are moved in an axial direction. The collar **34***a, b* may protrude slightly beyond the margin of the housing **20** and is acted upon when the elongated members **40***a, b* are moved in an angular or radial direction. As with the central flexible element **50** one or both of the flexible elements **30***a, b* may be constructed form a Newtonian material whereby transverse strain in response to axial strain is described by Poisson's ratio.

As shown in FIG. **10**A an inner surface **32***a, b* of the central region **36***a, b* of the collar **34***a, b* contacts an outer surface **46***a, b* of the flange **42***a, b* when the elongated members **40***a, b* are in a neutral position, for example, when the spine is at rest. Alternatively, a space may exist between the surfaces **32***a, b* and **46***a, b*, not shown in the drawings, to allow for greater unrestricted axial movement of elongated members **40***a, b*. FIG. **10**B illustrates the elongated members **40***a, b* subjected to an axial force causing the members **40***a, b* to move distally in the direction of arrow **61** such as would be experience when the spine is flexed. The outer surfaces of flanges **46***a, b* pushes on the flexible members **30***a, b* at contact surfaces **32** *a, b*. This in turn causes flexible members **30***a, b* to come into contact with the housing **20** and deform into interstitial space **28** and/or push the collar **34***a, b* through an opening in the ends **21***a, b* of the housing **20**. The expansion of the flexible members **30***a, b* into space **28** and through the ends **21***a, b* of housing **20** causes an exponential increase in resistance to axial loading. This allows for the restricted and stabilized movement of adjacent vertebral bodies.

A variety of shapes and sizes can be employed for the outer surfaces **46***a, b* of the flanges **42***a, b* and the corresponding contacting surface **32***a, b* of the flexible elements **30***a, b*. The shape of these surfaces may be varied in order to create a desired dynamic response. Providing a concave shape on surfaces **32***a, b* may lead to a more rapid deformation of the flexible elements **30***a, b* and, consequentially more rapid stiffening to limit the range of motion for the elongated members **40***a, b*. Alternatively, a convex shape may be utilized whereby the flanges **42***a, b* have a thinner profile allowing for the flexible elements **30***a, b* to be larger. This may provide for a greater range of motion to the elongated members **40***a, b*.

As shown in FIGS. **1-4** the housing **20** may be generally cylindrical and has openings at each end **21***a, b* allowing elongated members **40***a, b* to pass there through. In one embodiment of the invention, the housing **20** is constructed from a generally rigid material that will not deform under the physiological loading encountered within the spine. The housing **20** may be formed from a first **20***a* and a second **20***b* casing wherein each of the casings **20***a*, **20***b* have an opening at ends **21***a, b*. As shown in FIG. **4**, casing **20***a* includes a locking feature **22** that corresponds to a locking feature **24** on casing **20***b* so as to form a snap lock. Casing **20***b* also includes a plurality of expansion slots **26** that aid in assembly of the apparatus as will be described below.

As shown in FIG. **2**, the apparatus **10** is assembled by aligning the proximal ends of elongated members **40***a, b* with the central flexible element **50** such that the protrusions **52***a, b* correspond to slots **44***a, b*. The flexible elements **30***a, b*, which have an opening in the center corresponding to the cross sectional geometry of elongated members **40***a, b*, are then inserted over the distal ends of elongated members **40***a, b* and slid into place about the proximal end thereof or in proximity to flanges **42***a, b*. Thereafter, the distal ends of elongated members **40***a, b* are placed through the openings in the ends **21***a, b* of casings **20***a, b*. The openings in the ends **21** *a, b* are larger than the cross sectional geometry of the elongated members **40***a, b* creating a space between the elongated members **40***a, b* and the housing **20**. Casings **20***a, b* are placed together and inward pressure applied thereon such that locking features **22** slides under locking feature **24** which moves in a radial direction as facilitated by expansion slots **26** locking casings **20***a, b* together. The casings can also be assembled by welding, bolting, threading, screwing, adhesive bonding, magnetic coupling, clamping, or twist locking. Once casing **20** is assembled, the proximal ends of members **40***a, b*, the central element **50**, the flexible elements **30***a, b* and the flanges **42***a,b* are contained therein. The collars **34***a, b* of flexible elements **30***a, b*, however, are located in the spaces between the housing **20** and members **40***a, b* and may slightly protrude through the space between the elongated members **40***a, b* and the openings at the ends **21***a, b* of the housing **20**.

FIG. **12** illustrates the apparatus **10** implanted in the spine between adjacent vertebral bodies **8***a, b* in order to provide stability to the joint existing between vertebrae **8***a, b*. Typically, stabilization devices such as apparatus **10** are mounted to the vertebral bodies **8***a, b* via an anchoring device **3**. Once mounted to the spine **2** the apparatus **10** serves to stabilize adjacent vertebral bodies while also allowing for motion.

As shown in FIGS. **10**A-B, when the spine **2** is moved in the direction of arrows **11** the elongated members **40***a, b* transfer force to the flexible elements **30***a,b* as described above allowing for a limited range of motion. As shown in FIGS. **11**A-B and **14** when the spine is moved in the direction of arrows **12** or placed in extension the elongated members **40***a, b* moved toward the central flexible element **50**. The central flexible element **50** expands into spaces **70** and under certain conditions, for example increased extension of the spine creating the dynamic response discussed above. As shown in FIG. **15**, the spine **2** is experiencing lateral or side bending, as indicated by the arrows **13**. Under the lateral loading shown in FIG. **15** apparatus **10***a* will transfer the loading forces to flexible members **30***a, b* while the apparatus **10***b* will transfer loading to the central flexible element **50**.

FIG. **16** shows the spine rotated about its axis in the direction of arrow **14**. Due to the apparatus **10** being mounted away from the axis of the spine the device **10** experiences shear loading. As shown in FIG. **17** the elongated members **40***a, b* are moved in the direction indicated by arrows **63**. As the elongated members **40***a, b* are moved, surfaces **48***a, b* and **54***a, b* shift relative to each other such that flange **42***a, b* is free to interact with additional flexible elements **30***a, b*. As the flanges **42***a, b* contact additional flexible elements **30***a, b*, they impinge upon the housing **20**. Thereafter, the additional flexible elements **30***a, b* resist movement in the manner described above with reference to the distal movement of the elongated members **40***a, b*. This dynamic response maintains the elongated members **40***a, b* roughly parallel to each other as the central flexible element **50** and the housing **20** rotate.

Apparatus **10** has been described above primarily with reference to unidirectional loading conditions. As shown in FIG. **18**, however, the apparatus **10** can handle loading in multiple directions simultaneously. For example, as shown in FIG. **13** the elongated members **40***a, b* are moved both distally and obliquely from each other causing the additional flexible elements **30***a, b* interact with the flanges **42***a, b* and the housing **20** in a manner as described above. The space between the housing **20** and the elongated members **40***a, b* into which collars **34***a, b* are placed allows elongated members **40***a, b* a range of angular motion that is restricted in the direction of movement by the additional flexible elements **30***a, b* whereby collars **34***a, b* act as a buffer between the housing **20** and the elongated members **40***a, b*.

Although the present invention has been described above with respect to particular preferred embodiments, it will be apparent to those skilled in the art that numerous modifications and variations can be made to these designs without departing from the spirit or essential attributes of the present invention. Accordingly, reference should be made to the appended claims, rather than to the foregoing specification, as indicating the scope of the invention. The descriptions provided are for illustrative purposes and are not intended to limit the invention nor are they intended in any way to restrict the scope, field of use or constitute any manifest words of exclusion.

What is claimed:

1. An apparatus comprising:

at least two elongated members having a distal and proximal end, the proximal end comprising a flange, wherein the flange comprises a proximal surface and a distal surface;

a first flexible element disposed between the proximal ends of the at least two elongated members, wherein the first flexible member has a first and a second outward facing surface and further wherein the proximal surface of each of the flanges interacts with at least one of the outward facing surfaces of the first flexible element to form an anti-torsional coupling;

first and second additional flexible elements, each additional flexible element having a collar at least partially surrounding the proximal end of a corresponding elongated member; and

a housing having a first and a second end encapsulating the proximal ends of said members such that the first flexible element and the first and second additional flexible elements are contained therein wherein the first collar protrudes through an opening in the first end of the housing.

2. The apparatus of claim **1** wherein the anti-torsional coupling further comprises at least one protrusion on each of the outer facing surfaces of the first flexible element and at least one corresponding recess on the proximal surface of each of the flanges that receives said at least one protrusion.

3. The apparatus of claim **2** wherein the at least one protrusion on a first of the outward facing surfaces of the first flexible element is oriented so as to be offset from the at least one protrusion on a second of the outward facing surfaces of the first flexible element at a pre-determined angle.

4. The apparatus of claim **2** wherein the at least one protrusion comprises a rib that transverses the outward facing surface.

5. The apparatus of claim **2** wherein the at least one protrusion comprises at least two transverse ribs that intersect.

6. The apparatus of claim **2** wherein the at least one protrusion comprises at least one polygon.

7. The apparatus of claim **1** wherein the proximal surface is generally convex and contacts a surface of the first flexible element.

8. The apparatus of claim **1** wherein the distal surface is generally concave and contacts a surface of the at least one additional flexible element.

9. The apparatus of claim **1** wherein the anti-torsional coupling further comprises at least one recess on each of the outer facing surfaces of the first flexible element and at least one corresponding protrusion on the inward surface of each of the flanges that receives said at least one recess.

10. The apparatus of claim **1** wherein the housing, the first flexible element and the first and second additional flexible elements cooperate to define a space to permit deformation of the first flexible element in a lateral direction.

11. A stabilization apparatus for implantation into a spine comprising:

a first and a second elongated member each having a distal and proximal end;

an enlarged region located at the proximal end of each elongated member, each enlarged region having a proximal and a distal face;

a first flexible element disposed between the enlarged regions of each elongated member, wherein the first flexible member has a first and a second outward facing surface and further wherein the proximal face of each of the enlarged regions interacts with at least one of the outward facing surfaces of the first flexible element to form an anti-torsional coupling;

a first and second additional flexible element at least partially surrounding the proximal end of a corresponding elongated member in proximity with the enlarged regions, wherein the first and second additional elements further comprise a collar; and

a housing encapsulating the first flexible element, the enlarged regions, and the additional flexible elements wherein the first flexible element and additional flexible elements interact with the enlarged regions and the housing to permit movement of the elongated members in a direction complimentary to the movement of the spine, wherein the collar of the first additional flexible element protrudes through an opening in a first end of the housing.

* * * * *